Abbreviated 510(k) Notification

MAR 2 2 2013

510(k): Surveyor S12 and S19 Device Summary

Submitter: **Date: November 6, 2012**

Chien Hui (Amy) Yang, Regulatory Affairs Engineer
Mortara Instrument, Inc.
7865 N. 86th Street
Milwaukee, WI 53224
FAX: (414) 354-4760
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Contact: Chien Hui (Amy) Yang (see above)

Trade Name: Mortara Surveyor Patient Monitor
Common Name: Patient Physiological Monitor (with Arrhythmia Detection or Alarms)
Classification Name: Monitor, Physiological Patient (with Arrhythmia Detection or Alarms)
Classification Regulation: 21 CFR §870.1025
Product Code: MHX

Legally marketed devices to which S.E. is claimed:

Mortara Surveyor Patient Monitor	Predicate 510(k) Number	Predicate Manufacturer / Model
Non-Invasive Blood Pressure component Impedance Respiration component Invasive Blood Pressure component Temperature component Functional Arterial Oxygen Saturation component End-Tidal & Inspired CO2 component	K090556	Spacelabs Healthcare / élance Vital Signs Monitor
ECG Monitoring	K090556	Spacelabs Healthcare / élance Vital Signs Monitor
	K060135	Mortara Instrument, Inc. / Surveyor Telemetry Central Station
12-Lead Resting ECG	K100127	Mortara Instrument, Inc. / ELI 230 Electrocardiograph
Cardiac Output	K012226	Schiller / ARGUS PB-1000 Monitoring System

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Description:

The Mortara Instrument, Inc. Surveyor Patient Monitoring System (S12 and S19) is a portable patient monitors intended to be used by clinicians and medical qualified personnel for monitoring ECG, Respiration, NIBP, Temperature, SPO2, Invasive Blood Pressure, End-Tidal & Inspired CO2, 12-lead resting ECG and cardiac output. Models within the Mortara Surveyor family come in two different sized viewing areas (11.6" and 18.5") and offer selected monitoring features. See the Product Specification for identified models and monitoring features.

Central Station:

A secure Mortara protocol over an Ethernet connection allows the Mortara Surveyor Patient Monitor to exchange patient information with the Mortara Surveyor Central Station. This allows monitoring of the Surveyor S12/S19 at a central workstation.

Technology Comparison:

The Mortara Surveyor utilizes the same or similar technology for each parameter as utilized by the predicate devices.

Intended Use:

The Mortara Surveyor Patient Monitor is a prescription device intended to be used by knowledgeable healthcare professionals within a healthcare facility. It is designed for continuous monitoring in either stationary or portable applications. It is intended to be used by clinicians and medical qualified personnel for monitoring ECG, Respiration, NIBP, Temperature, SPO2, Invasive Blood Pressure, End-Tidal & Inspired CO2, 12-lead resting ECG and cardiac output.

Indications for Use:
The Mortara Surveyor Patient Monitor is indicated for use in adult & pediatric patient populations.
The Mortara Surveyor Patient Monitor facilitates the monitoring of:

- Non-invasive blood pressure
- Impedance respiration
- Invasive blood pressure
- Temperature
- Functional arterial oxygen saturation (SpO_2)
- End-tidal & inspired CO_2
- ECG monitoring with arrhythmia & ST-segment
- 12-Lead resting ECG
- Cardiac output

The Mortara Surveyor Patient Monitor is a prescription device intended to be used by healthcare professionals in all areas of a healthcare facility.

Performance Testing:
Sterilization Validation:
The Mortara Surveyor Patient Monitor is not sterilized or sterilizable, and therefore this section does not apply to the monitor itself.

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Shelf Life Testing:
The Mortara Surveyor Patient Monitor is not sterilized or sterilizable, and therefore this section does not apply to the monitor itself.

Biocompatibility Testing:
The S12 and S19 patient contacting components use the same materials used on other products that Mortara has used historically and/or has been cleared as substantially equivalent previously.

Software Testing:
Software for the Mortara Surveyor Patient Monitor was designed and developed according to a robust software development process, and was rigorously verified and validated. Test results indicated that the Mortara Surveyor Patient Monitor complies with its predetermined specification.

Electrical Safety:
The Mortara Surveyor Patient Monitor was tested for patient safety in accordance with applicable Standards. Test results indicated that the Mortara Surveyor Patient Monitor complies with its predetermined specification.

Electromagnetic Compatibility Testing:
The Mortara Surveyor Patient Monitor was tested for EMC in accordance with applicable Standards. Test results indicated that the Mortara Surveyor Patient Monitor complies with its predetermined specification.

Performance Testing – Bench:
The Mortara Surveyor Patient Monitor was tested in accordance with internal requirements and procedures, and test results indicated that the device complies with the predetermined requirements. This testing includes performance and functional, environmental, and vibration/ shock testing.

Performance Testing – Animal:
Animal performance testing was not performed and is not necessary to demonstrate safety and effectiveness of the Mortara Surveyor Patient Monitor.

Performance Testing – Clinical:
Clinical performance testing was not performed and is not necessary to demonstrate safety and effectiveness of the Mortara Surveyor Patient Monitor.

Conclusion:
Based upon a comparison of devices and performance testing results, the Mortara Surveyor Patient Monitor is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 22, 2013

Mortara Instrument, Inc.
c/o Ms. Amy Yang
7865 North 86th St.
Milwaukee, WI 53224

Re: K123556
Trade/Device Name: Surveyor Patient Monitor
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia detector and alarm (including ST-segment measurement and alarm)
Regulatory Class: Class II (two)
Product Code: MHX
Dated: February 27, 2013
Received: February 28, 2013

Dear Ms. Yang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Owen P. Faris -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123556

Device Name: **Mortara Surveyor Patient Monitor**

Indications for Use:

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- Non-invasive blood pressure
- Impedance respiration
- Invasive blood pressure
- Temperature
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- End-tidal & inspired CO_2
- ECG monitoring with arrhythmia & ST-segment
- 12-Lead resting ECG
- Cardiac output

The Mortara Surveyor Patient Monitor is a prescription device intended to be used by healthcare professionals in all areas of a healthcare facility.

Prescription Use ___X____ (21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Owen P. Faris -S
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Concurrence of CDRH, Office of Device Evaluation (ODE)